UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

CITY OF ALABASTER, ALABAMA,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; McKESSON CORPORATION; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; NORAMCO, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; PAR PHARMACEUTICAL, INC.; PAR PHARMACEUTICAL COMPANIES, INC. f/k/a PAR PHARMACEUTICAL HOLDINGS, INC.; WEST-WARD PHARMACEUTICALS CORP. and WEST-WARD PHARMACEUTICAL CORP. n/k/a PHARMACEUTICALS, INC.; MYLAN PHARMACEUTICALS, INC.; MYLAN BERTEK PHARMACEUTICALS INC.; INDIVIOR INC.; WALGREENS BOOTS ALLIANCE, INC. a/k/a WALGREEN CO.; WALMART INC f/k/a WAL-MART STORES, INC.; CVS HEALTH CORPORATION.

Defendants.

CIVIL ACTION NO. _____

JURY TRIAL DEMANDED

COMES NOW, the City of Alabaster, Alabama, and files the foregoing action, as follows:

I. PRELIMINARY STATEMENT

1. Plaintiff provides essential services for their citizens and residents, including law enforcement, emergency medical assistance, services for families and children, public assistance, public welfare, and other care and services for the health, safety and welfare of their citizens and residents. The rising numbers of people addicted to opioids have led to significantly increased costs, as well as a dramatic increase of social problems, including, but not limited to, drug abuse and the commission of criminal acts to obtain opioids.[1]

2. Opioids include brand-name drugs like Oxycontin and Percocet, as well as generic drugs like oxycodone and hydrocodone. These drugs are derived from or possess properties similar to opium and heroin, and, as such, they are highly addictive and dangerous.

3. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid overdose deaths and addictions.[2]

4. Plaintiff brings this civil action to recover damages from the Defendants, who are manufacturers and distributors of opioids, and to eliminate the hazard to public health and safety caused by the opioid epidemic, to abate the nuisance caused thereby, and to recoup monies that have been spent, or will be spent, because of Defendants' false, deceptive and unfair marketing and unlawful diversion and distribution of prescription opioids.

[1] As used herein, the term "opioid" or "opioids" refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.

[2] *See* Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies,* 374 N. Eng. J. Med. 1253 (2016).

II. PARTIES

A. PLAINTIFF

5. The City of Alabaster, Alabama has been damaged, and continues to be damaged by the Defendants' conduct.

6. The City of Alabaster, Alabama (hereinafter referred to as "Plaintiff" or "Plaintiff City") is a municipal corporation organized under the laws of the State of Alabama and authorized to bring the causes of action herein. Ala. Code § 11-40-1 ("All municipal organizations now existing in the State of Alabama . . . shall sue and be sued . . . Such municipal corporations shall be invested with the full powers, duties, and authority granted in this title."). Plaintiff is responsible for the public health, safety, and welfare of their citizens.

7. Plaintiff is specifically authorized to seek common law public nuisance remedies available under Alabama law. See Ala. Code §§ 6-5-122 ("All municipalities in the State of Alabama may commence an action in the name of the city to abate or enjoin any public nuisance injurious to the health, morals, comfort, or welfare of the community or any portion thereof."); 11-47-118; ("Municipalities may maintain a civil action to enjoin and abate any public nuisance, injurious to the health, morals, comfort or welfare of the community or any portion thereof."); 11-47-117 ("All cities and towns of this state shall have the power to prevent injury or annoyances from anything dangerous or offensive or unwholesome and to cause all nuisances to be abated and assess the cost of abating the same against the person creating or maintaining the same.").

8. In Plaintiff City, opioid abuse, addiction, morbidity and mortality has created a serious public health and safety crisis, is a public nuisance, and the diversion of opioids into the illicit market causes or contributes to this public nuisance.

9. The distribution and diversion of opioids into Plaintiff City created the foreseeable opioid crisis and public nuisance for which Plaintiff seeks relief.

10. Plaintiff has sustained economic damages as a direct and proximate result of Defendants' conduct as alleged herein. Categories of past and continuing damages include but are not limited to; (1) costs associated with law enforcement and public safety relating to the opioid epidemic: (2) costs for providing emergency services, medical care, therapeutic care, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (3) costs for prescription drug purchases; and (4) such other costs as may be proven in this litigation.

11. Plaintiff also seeks the means to abate the opioid epidemic created by Defendants' wrongful and/or unlawful conduct.

12. Plaintiff is authorized by law to abate any nuisance and prosecute any person or entity who creates, continues or contributes to such nuisance, and to prevent injury and annoyance from such nuisance.

13. Plaintiff has standing to bring this action and recover damages incurred as a result of Defendants' acts and omissions.

14. Plaintiff adopts and incorporates the Master Complaint (MDL 2804), including all factual allegations and legal claims.

B. MANUFACTURER DEFENDANTS

15. At all relevant times, certain Defendants named below packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn, or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. These Defendants (the

"Manufacturer Defendants") manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders. Plaintiff notes that Insys Therapeutics, Inc., and its affiliated debtors ("Insys"); Mallinckrodt PLC, and its affiliated debtors ("Mallinckrodt"); and Purdue Pharma L.P. and its affiliated debtors ("Purdue") have filed for Chapter 11 Bankruptcy Protection, otherwise Plaintiff would incorporate these entities among the manufacturer defendants in this case. While Insys, Mallinckrodt, and Purdue are not named Defendants in this action, nor are their numerous related entities, Plaintiff herein identifies each as a non-party co-conspirator. Plaintiff's acknowledgement of the purported stay of proceedings against those entities is not a waiver of any claims against Insys, Mallinckrodt, Purdue, or their numerous related entities relative to their manufacture, sales and marketing of opioids. Indeed, Plaintiff intends to pursue all available claims against these entities for which they may be liable.

16. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania, which is registered to do business in Alabama. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. in October 2011. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania, which is registered to do business in Alabama and is a wholly owned subsidiary of Teva Ltd. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to collectively as "Cephalon."

17. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the United States. Actiq has been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already

receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain."[3] Fentora has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."[4] In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay $425 million.[5]

18. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

19. Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo.[6] Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 - the year immediately following the Cephalon acquisition -

---

[3] *Highlights of Prescribing Information, ACTIQ (fentanyl citrate) oral transmucosal lozenge, CII* (2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf.

[4] *Highlights of Prescribing Information, FENTORA (fentanyl citrate) buccal tablet, CII* (2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf.

[5] Press Release, U.S. Dep't of Justice, Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept 29, 2008), https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html.

[6] *E.g.*, ACTIQ, http://www.actiq.com/ (displaying logo at bottom-left) (last visited Aug. 21, 2017).

attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales," including inter alia sales of Fentora.[7] Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder.

20. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation registered to do business in Alabama with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products.

21. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to collectively as "Janssen."

[7] Teva Ltd., Annual Report (Form 20) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

22. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

23. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania, and is a wholly owned subsidiary of Endo Health Solutions Inc. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to collectively as "Endo."

24. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

25. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired ALLERGAN PLC in March 2015, and the combined company changed its name to ALLERGAN PLC as of June 2015. Before that, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then ACTAVIS PLC in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation

with its principal place of business in Corona, California, and is a wholly owned subsidiary of ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey, which is registered to do business in Alabama, and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by ALLERGAN PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, ALLERGAN PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. ALLERGAN PLC, ACTAVIS PLC, ACTAVIS, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to collectively as "Allergan."

26. Allergan manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States. Allergan acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

27. MALLINCKRODT, LLC, a non-party co-conspirator, is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business in St. Louis, Missouri. Mallinckrodt who currently enjoys the protection of a bankruptcy stay and is therefore not a named Defendant in this case.

28. Mallinckrodt, LLC is a wholly owned subsidiary of MALLINCKRODT, PLC, which is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Mallinckrodt, PLC and Mallinckrodt, LLC do business as Mallinckrodt

Pharmaceuticals. Mallinckrodt, PLC and Mallinckrodt, LLC are referred to collectively as "Mallinckrodt."

29. Mallinckrodt manufactures, markets, and sells drugs in the United States including Exalgo, Roxicodone, and generic oxycodone, of which it is one of the largest manufacturers. In July 2017 Mallinckrodt agreed to pay $35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

30. INSYS THERAPEUTICS, INC., a non-party co-conspirator, is a Delaware company with its principal place of business in Chandler, Arizona, which is registered to do business in Alabama. Insys Therapeutics, Inc. is referred to as "Insys."

C. DISTRIBUTOR DEFENDANTS

31. At all relevant times, certain Defendants named below distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. These Defendants (the "Distributor Defendants") failed to comply with federal and/or state law. Plaintiff alleges the unlawful conduct by the Distributor Defendants is responsible for the volume of prescription opioids entering into and plaguing Plaintiff City.

32. McKESSON CORPORATION ("McKesson"), at all relevant times, operated as a licensed pharmacy wholesaler in Alabama. McKesson is registered with the Alabama Secretary of State as a Delaware corporation. McKesson has its principal place of business located in San Francisco, California.

33. CARDINAL HEALTH, INC. ("Cardinal") at all relevant times, operated as a licensed pharmacy wholesaler in Alabama. Cardinal is registered through various entities including Cardinal Health 100, Inc. with the Alabama Secretary of State as an Indiana corporation,

with its principal office located in Dublin, Ohio. Cardinal Health, Inc. is an Indiana corporation with its principal place of business in Dublin, Ohio.

34. AMERISOURCEBERGEN DRUG CORPORATION ("AmerisourceBergen"), at all relevant times, operated as a licensed pharmacy wholesaler in Alabama. AmerisourceBergen is registered with the Alabama Secretary of State as a Delaware corporation which may be served through its registered agent for service of process. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania.

35. The data which reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. *See Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015). Neither the DEA[8] nor the wholesale distributors[9] will voluntarily disclose the data necessary to identify with specificity the transactions which will form the evidentiary basis for the many claims asserted herein.

36. Consequently, Plaintiffs have named the three (3) wholesale distributors (i.e., AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation) which dominate 85% of the market share for the distribution of prescription opioids, whose principal business is the nationwide wholesale distribution of prescription drugs. See Fed. Trade Comm'n v. Cardinal Health, Inc., 12 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal Health, Inc., McKesson Corporation, and AmerisourceBergen Drug Corporation predecessors). Each has been

[8] Declaration of Katherine L. Myrick, Chief, Freedom of Information (FOI)/Privacy Act Unit ("SARF"), FOI, Records Management Section ("SAR"), Drug Enforcement Administration (DEA), United States Department of Justice (DOJ), *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 23) (filed 02/06/14) (noting that ARCOS data is "kept confidential by the DEA").

[9] *See* Declaration of Tina Lantz, Cardinal Health VP of Sales Operation, *Madel v. USDOJ*, Case 0:13-cv-02832- PAM-FLN, (Document 93) (filed 11/02/16) ("Cardinal Health does not customarily release any of the information identified by the DEA notice letter to the public, nor is the information publicly available. Cardinal Health relies on DEA to protect its confidential business information reported to the Agency.").

investigated and/or fined by the DEA for the failure to report suspicious orders. Plaintiff has reason to believe each has engaged in unlawful conduct which resulted in the diversion of prescription opioids into Plaintiff City and that discovery will likely reveal others who likewise engaged in unlawful conduct. Plaintiff names each of these corporations herein as defendants and place the industry on notice that the Plaintiff is acting to abate the public nuisance plaguing the community. Plaintiff will request expedited discovery pursuant to Rule 26(d) of the Federal Rules of Civil Procedure to secure the data necessary to reveal and/or confirm the identities of the wholesale distributors, including data from the ARCOS database.

D. ADDITIONAL DEFENDANTS

37. The Additional Defendants are listed as follows: PAR PHARMACEUTICAL, INC.; PAR PHARMACEUTICAL COMPANIES, INC. f/k/a PAR PHARMACEUTICAL HOLDINGS, INC.; WEST-WARD PHARMACEUTICALS CORP. and WEST-WARD PHARMACEUTICAL CORP. n/k/a HIKMA PHARMACEUTICALS, INC.; MYLAN PHARMACEUTICALS, INC.; MYLAN BERTEK PHARMACEUTICALS INC.; INDIVIOR INC.; WALGREENS BOOTS ALLIANCE, INC. a/k/a WALGREEN CO.; WALMART INC f/k/a WAL-MART STORES, INC.; CVS HEALTH CORPORATION. The Additional Defendants are either Manufacturing Defendants, Distributor Defendants or Pharmacy Defendants. The factual allegations, legal claims, jurisdiction, principal place of business and venue for the Additional Defendants can be found in the Master Complaint.

III. JURISDICTION AND VENUE

38. Plaintiff recognizes the foregoing matter is directly related to such multidistrict litigation stemming from the nationwide opioid epidemic and therefore, acknowledges original jurisdiction over this action for purposes of pretrial proceedings is pursuant to 28 U.S.C. § 1407,

and Case Management Order One entered in In Re: National Prescription Opiate Litigation (1:17-CV-2804, N.D. Ohio, April 11, 2018). Plaintiff does not object to transfer thereto for pretrial purposes only.

39. Jurisdiction and venue for remand or trial of this action is proper in the Northern District of Alabama ("NDAL"). All Defendants do business by agent in Alabama and are part of a series of distribution agreements providing opioid drugs to distribution centers, pharmacies, and healthcare professionals through the State of Alabama. The amount in controversy exceeds the jurisdictional minimum of the NDAL.

40. Venue is proper in the NDAL because a significant amount of those actions giving rise to the claims for relief arose in the NDAL, and all other related claims are also proper in the NDAL as additional claims against the named Defendants.

41. NDAL has personal jurisdiction over the Defendants because they conduct business in Alabama, directly and through the purposeful direction of their actions towards Alabama and have the requisite minimum contacts with Alabama necessary to constitutionally permit the NDAL to exercise jurisdiction.

VI. TOLLING AND FRAUDULENT CONCEALMENT

42. Plaintiff continues to suffer harm from the unlawful actions by the Defendants.

43. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The harm is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated.

44. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status and to continue generating profits. The Defendants affirmatively assured the public that they are working to curb the opioid epidemic.

45. The Defendants not only have acknowledged that they understood their obligations under the law, but they further publicly affirmed their claim that their conduct was in compliance with those obligations.

46. The Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, which would confirm the extent of their wrongful and illegal activities.

47. The Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Defendants invented the term "pseudo-addiction" and promoted it to an unsuspecting medical community. Defendants provided the medical community with false and misleading information about ineffectual medical strategies to avoid or control opioid addiction. Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales.

48. The medical community and consumers were duped by the Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the state of Alabama.

49. Plaintiff and the citizens of the state of Alabama reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

50. Plaintiff's claims are equitably tolled because Defendants knowingly and fraudulently concealed the facts and their wrongful acts, and the material information pertinent to their discovery, which Defendants concealed them from Plaintiff. Plaintiff did not know, or could not have known through the exercise of reasonable diligence, of its claims, as a result of Defendants' conduct.

51. The purpose of the statutes of limitations period is satisfied because Defendants cannot claim prejudice due to late filing where the Plaintiff filed suit promptly upon discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

52. In light of their statements to the media, in legal filings, and settlements, Defendants had actual and constructive knowledge that their conduct was deceptive, in that they consciously concealed the schemes set forth herein.

53. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. As a result of the above, Plaintiff was unable to obtain vital information bearing on its claims absent any fault or lack of diligence on their part.

IV. ADDITIONAL ALLEGATIONS COMMON TO ALL COUNTS

54. The past two decades have been characterized by increasing abuse and diversion of prescription drugs, including opioid medications, in the United States.[10]

[10] *See* Richard C. Dart et al, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372

55. Prescription opioids have become widely prescribed. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.[11]

56. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention, declared prescription painkiller overdoses at epidemic levels. The News Release noted:

a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.

b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).

c. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.

d. Almost 5,500 people start to misuse prescription painkillers every day.[12]

57. The number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population.[13]

58. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. In 2016, drug overdoses killed roughly 64,000 people in the United States, an increase of more than 22 percent over the 52,404

N. Eng. J. Med. 241 (2015).

[11] Katherine M. Keyes at al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, 104 Am. J. Pub. Health e52 (2014).

[12] *See* Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

[13] *See* Califf et al., *supra* note 3.

drug deaths recorded the previous year.[14]

59. Moreover, the CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin.[15]

60. Heroin is pharmacologically similar to prescription opioids. The majority of current heroin users report having used prescription opioids non-medically before they initiated heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use.[16]

61. The CDC reports that drug overdose deaths involving heroin continued to climb sharply, with heroin overdoses more than tripling in 4 years. This increase mirrors large increases in heroin use across the country and has been shown to be closely tied to opioid pain reliever misuse and dependence. Past misuse of prescription opioids is the strongest risk factor for heroin initiation and use, specifically among persons who report past-year dependence or abuse. The increased availability of heroin, combined with its relatively low price (compared with diverted prescription opioids) and high purity appear to be major drivers of the upward trend in heroin use and overdose.[17]

---

[14] *See* Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Provisional Counts of Drug Overdose Deaths, (August 8, 2016), https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf.

[15] *See* Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/index.html (last updated July 7, 2015).

[16] *See* Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016).

[17] *See* Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014*, 64 Morbidity & Mortality Wkly. Rep. 1378 (2016).

62. The societal costs of prescription drug abuse are "huge."[18]

63. Across the nation, local governments are struggling with a pernicious, ever-expanding epidemic of opioid addiction and abuse. Every day, more than 90 Americans lose their lives after overdosing on opioids.[19]

64. The National Institute on Drug Abuse identifies misuse and addiction to opioids as "a serious national crisis that affects public health as well as social and economic welfare."[20] The economic burden of prescription opioid misuse alone is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.[21]

65. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.[22]

66. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or

---

[18] *See* Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. Justice*, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10 [hereinafter Brief of HDMA].

[19] Opioid Crisis, NIH, National Institute on Drug Abuse (available at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis, last visited April 9, 2018) ("Opioid Crisis, NIH") (citing at note 1 Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. MMWR Morb Mortal Wkly Rep 2016;65:1445–1452. DOI: http://dx.doi.org/10.15585/mmwr.mm655051e1)

[20] Opioid Crisis, NIH.

[21] *Id.* (citing at note 2 Florence CS, Zhou C, Luo F, Xu L, The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013, *MED CARE* 2016;54(10):901-906, doi:10.1097/MLR.0000000000000625).

[22] *See* Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 Morbidity & Mortality Wkly. Rep. 1445 (2016).

emergency department have increased by a factor of six in the past 15 years.[23]

67. Every day brings a new revelation regarding the depth of the opioid plague: just to name one example, the New York Times reported in September 2017 that the epidemic, which now claims 60,000 lives a year, is now killing babies and toddlers because ubiquitous, deadly opioids are "everywhere" and mistaken as candy.[24]

68. The epidemic of prescription pain medication and heroin deaths is devastating families and communities across the country.[25] Meanwhile, the manufacturers and distributors of prescription opioids extract billions of dollars of revenue from the addicted American public while public entities experience tens of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic.

69. Defendants have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct is causing and/or continuing to the national, state, and local opioid epidemic.

70. The State of Alabama has been impacted severely by the national opioid crisis.

71. Alabama has an opioid prescription rate of 142.9 per 100 persons, which ranks first in the country (U.S. median rate: 82.5).[26]

---

[23] *See* Volkow & McLellan, *supra* note 1.

[24] Julie Turkewitz, 'The Pills are Everywhere': How the Opioid Crisis Claims Its Youngest Victims, N.Y. Times, Sept. 20, 2017 ("'It's a cancer,' said [grandmother of dead one-year old], of the nation's opioid problem, 'with tendrils that are going everywhere.'").

[25] *See* Presidential Memorandum – Addressing Prescription Drug Abuse and Heroin Use, 2015 Daily Comp. Pres. Doc. 743 (Oct. 21, 2015), https://www.gpo.gov/fdsys/pkg/DCPD-201500743/pdf/DCPD-201500743.pdf.

[26] *See* Leonard J. Paulozzi, M.D., *et al., Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines – United States, 2012*, Morbidity and Mortality Weekly Report, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (July 4, 2014). The combination of hydrocodone, oxycodone, and benzodiazepines is referred to as the "holy

72. As reported by the Centers for Disease Control and Prevention, Alabama has been among the states hardest hit by the opioid epidemic for years. From 1999 to 2016, Alabama's death rate due to drug overdose has increased more than 400 percent.[27]

73. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Because of the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

74. Each Manufacturer Defendant has conducted, and has continued to conduct, a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

75. The Manufacturer Defendants have made false and misleading claims, contrary to the language on their drugs' labels, regarding the risks of using their drugs that: (1) downplayed the serious risk of addiction; (2) created and promoted the concept of

trinity" and significantly increases the risk of harm to those that abuse prescription pills.

[27] Centers for Disease Control and Prevention (CDC) National Center for Health Statistics.

"pseudoaddiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. The Manufacturer Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Manufacturer Defendants' claims.

76. The Manufacturer Defendants have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Manufacturer Defendants recruited for their support of their marketing messages, and through unbranded marketing and industry-funded front groups.

77. Defendants' efforts have been successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated $11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded $8 billion in revenue annually since 2009.[28] In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors... [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate

[28] *See* Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, Fortune, Nov. 9, 2011, http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/; David Crow, *Drugmakers Hooked on $10bn Opioid Habit*, Fin. Times, Aug. 10, 2016, https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95.

pain."[29] This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin.

78. The Manufacturer Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

79. The Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in and around the State, including in Plaintiff's Community. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the State and Plaintiff's Community.

80. The Manufacturer Defendants employed the same marketing plans and strategies and deployed the same messages in and around the State, including in Plaintiff's Community, as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that the Manufacturer Defendants' messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

[29] Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), http://turnthetiderx.org/.

81. The Manufacturer Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. The Manufacturer Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

82. The Manufacturer Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Manufacturer Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, upon information and belief, the Manufacturer Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

83. Many of the Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker, chef, and teacher, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Upon information and belief, Purdue also ran a series of ads, called "Pain Vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

84. The Manufacturer Defendants promoted the use of opioids for chronic pain

through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. They devoted massive resources to direct sales contacts with doctors. Upon information and belief, in 2014 alone, the Manufacturer Defendants spent in excess of $168 million on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000.

85. The Manufacturer Defendants' detailing to doctors is effective. Studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. The Manufacturer Defendants purchase, manipulate and analyze some of the most sophisticated data available in any industry, data available from IMS Health Holdings, Inc., to track the rates of initial prescribing and renewal by individual doctors, which in turn allows them to target, tailor, and monitor the impact of their core messages.

86. The Manufacturer Defendants' detailers have been reprimanded for their deceptive promotions. In March 2010, for example, the FDA found that Actavis had been distributing promotional materials that "minimize[] the risks associated with Kadian and misleadingly suggest[] that Kadian is safer than has been demonstrated." Those materials in particular "fail to reveal warnings regarding potentially fatal abuse of opioids, use by individuals other than the patient for whom the drug was prescribed."[30]

87. The Manufacturer Defendants indirectly marketed their opioids using unbranded advertising, paid speakers and "key opinion leaders" ("KOLs"), and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to

[30] Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18,2010), http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.

hereinafter as "Front Groups").

88. The Manufacturer Defendants deceptively marketed opioids in the State of Alabama through unbranded advertising – e.g., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, the Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain.

89. The Manufacturer Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. The Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

90. Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

91. The Manufacturer Defendants worked through third parties they controlled by: (a)

funding, assisting, encouraging, and directing doctors who served as KOLs, and (b) funding, assisting, directing, and encouraging seemingly neutral and credible Front Groups. The Manufacturer Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors, and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, CME programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, the Manufacturer Defendants persuaded doctors and patients that what they have long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and that the compassionate treatment of pain required opioids.

92. In 2007, multiple States sued non-party co-conspirator, Purdue for engaging in unfair and deceptive practices in its marketing, promotion, and sale of OxyContin. Certain states settled their claims in a series of Consent Judgments that prohibited Purdue from making misrepresentations in the promotion and marketing of OxyContin in the future. By using indirect marketing strategies, however, Purdue intentionally circumvented these restrictions. Such actions include contributing the creation of misleading publications and prescribing guidelines which lack reliable scientific basis and promote prescribing practices which worsened the opioid crisis.

93. Doctors who are "pro-opioid" are one of the avenues that the Manufacturer Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website "In the Face of Pain" failed to disclose that doctors who provided

testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

94. The Manufacturer Defendants also entered arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of the Manufacturer Defendants, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted the Manufacturer Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

95. These Front Groups depended on the Manufacturer Defendants for funding and, in some cases, for survival. The Manufacturer Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, the Manufacturer Defendants made sure that the Front Groups would generate only the messages that the Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

96. Defendants Cephalon, Endo, Janssen, and non-party co-conspirator Purdue utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), the Center for Practical Bioethics ("CPB"), the

U.S. Pain Foundation ("USPF") and Pain & Policy Studies Group ("PPSG").[31]

97. The most prominent of the Manufacturer Defendants' Front Groups was the American Pain Foundation ("APF"), which, upon information and belief, received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012, primarily from Endo and Purdue. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television, and the internet – to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach citizens of the State and Plaintiff's Community.

98. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, upon information and belief, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit.

[31] *See generally, e.g.*, Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep't of Health and Human Servs., (May 5, 2015), https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf

99. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. Upon information and belief, it was often called upon to provide "patient representatives" for the Manufacturer Defendants' promotional activities, including for Purdue's Partners Against Pain and Janssen's Let's Talk Pain. APF functioned largely as an advocate for the interests of the Manufacturer Defendants, not patients. Indeed, upon information and belief, as early as 2001, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

100. Upon information and belief, on several occasions, representatives of the Manufacturer Defendants, often at informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived because of these communications.

101. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and the Manufacturer Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."[32]

[32] Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies' Ties to Pain Groups*, Wash. Post, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html.

102. Another front group for the Manufacturer Defendants was the American Academy of Pain Medicine ("AAPM"). With the assistance, prompting, involvement, and funding of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

103. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

104. Upon information and belief, AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry supported KOLs Perry Fine and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation.

105. The Manufacturer Defendants were able to influence AAPM through significant and regular funding and via the leadership of pro-opioid KOLs within the organization.

106. In 1996, AAPM and APS jointly issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," which endorsed opioids to treat chronic pain and claimed that the risk of a patients' addiction to opioids was low. Dr. Haddox, who co- authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and, upon information and belief, was taken down from AAPM's website only after a doctor complained.[33]

107. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.[34] Treatment guidelines have been relied upon by doctors, especially the general practitioners and family doctors targeted by the Manufacturer Defendants. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

108. At least fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.[35] One panel

[33] *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 Clinical J. Pain 6 (1997).

[34] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

[35] *Id.*

member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited hundreds of times in academic literature, were disseminated in the State and/or Plaintiff's Community during the relevant time period, are available online, and were reprinted in the Journal of Pain. The Manufacturer Defendants widely referenced and promoted the 2009 Guidelines without disclosing the lack of evidence to support them or the Manufacturer Defendants financial support to members of the panel.

109. The Manufacturer Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which the Manufacturer Defendants determined would reduce prescribing.

110. To falsely assure physicians and patients that opioids are safe, the Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use,

particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low risk because most patients would not become addicted, and because those at greatest risk for addiction could be identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. The Manufacturer Defendants have not only failed to correct these misrepresentations, but they also continue to make them today.

111. Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and non-party co-conspirator, Purdue Pharma L.P., have entered into settlement agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint. Yet even afterward, each Manufacturer Defendant continued to misrepresent the risks and benefits of long-term opioid use in the State and Plaintiff's Community, and each continues to fail to correct its past misrepresentations.

112. Some illustrative examples of the Manufacturer Defendants' false, deceptive, and unfair claims about the purportedly low risk of addiction include:

a. Actavis's predecessor caused a patient education brochure, Managing Chronic Back Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond;

b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People

Living with Pain (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online;[36]

c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Upon information and belief, another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications;

d. upon information and belief, Endo distributed a pamphlet with the Endo logo entitled Living with Someone with Chronic Pain, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem;"

e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain;"

f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated;"

g. Non-party co-conspirator Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "[m]isconceptions about opioid addiction;"[37]

h. consistent with the Manufacturer Defendants' published marketing materials, upon information and belief, detailers for Endo, Janssen, Cephalon and non-party co-conspirator Purdue in the State and Plaintiff's Community minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely

[36] Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

[37] Am. Pain Found., *A Policymaker's Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker's Guide*], http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

did not correct the misrepresentations noted above; and

i. seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants' Front Groups APF and NFP argued in an amicus brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy;[38]

113. These claims are contrary to longstanding scientific evidence. A 2016 opioid-prescription guideline issued by the CDC (the "2016 CDC Guideline") explains that there is "[e]xtensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose . . .)."[39] The 2016 CDC Guideline further explains that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[40]

114. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for extended-release and long-acting ("ER/LA") opioids in 2013 and for immediate release ("IR") opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse,

[38] Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.

[39] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[40] *Id.* at 2, 25.

and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed.[41]

115. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder.[42] Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State of New York found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free, however, to make those statements in this State.

116. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, the Manufacturer Defendants also fostered a fundamental misunderstanding of the signs of addiction. Specifically, the Manufacturer Defendants misrepresented, to doctors and

---

[41] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., v. U.S. Dep't of Health and Human Servs., to Andrew Koldny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf.; Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016), https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf.

[42] Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc. (*Assurance No. 15-228), at 16, https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

patients, that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain (i.e., pseudoaddiction) – and instructed doctors to increase the opioid prescription dose for patients who were already in danger.

117. To this end, one of Purdue's employees, Dr. David Haddox, invented a phenomenon called "pseudoaddiction." KOL Dr. Portenoy popularized the term. Examples of the false, misleading, deceptive, and unfair statements regarding pseudoaddiction include:

a. Cephalon and Purdue sponsored Responsible Opioid Prescribing (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudo-addiction, rather than true addiction.[43] The 2012 edition, which remains available for sale online, continues to teach that pseudo-addiction is real;[44]

b. Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudo-addiction . . . refers to patient behaviors that may occur when pain is under-treated . . . Pseudo-addiction is different from true addiction because such behaviors can be resolved with effective pain management;"

c. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 entitled "Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia," which, upon information and belief, promoted pseudo-addiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials;

d. Purdue published a pamphlet in 2011 entitled Providing Relief, Preventing Abuse, which, upon information and belief, described pseudo-addiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated;" and

e. Upon information and belief, Purdue sponsored a CME program titled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse". In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that

[43] Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2007) at 62.

[44] *See* Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2d ed. 2012)

> because of pseudo-addiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

118. In the 2016 CDC Guideline, the CDC rejects the validity of the pseudo-addiction fallacy invented by a Purdue employee as a reason to push more opioid drugs onto already addicted patients.[45]

119. In addition to misstating the addiction risk and inventing the pseudo-addiction falsehood, a third category of false, deceptive, and unfair practice is the Manufacturer Defendants' false instructions that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because the Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Illustrative examples include:

a. Endo paid for a 2007 supplement in the Journal of Family Practice written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled Pain Management Dilemmas in Primary Care: Use of Opioids, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts;

b. Non-party co-conspirator Purdue, upon information and belief, sponsored a 2011 webinar, Managing Patient's Opioid Use: Balancing the Need and Risk, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths;"

c. As recently as 2015, upon information and belief, Purdue has represented in

[45] *Id.* at 2, 25.

> scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

120. The 2016 CDC Guideline confirms the falsity of these claims. The Guideline explains that there are no studies assessing the effectiveness of risk mitigation strategies "for improving outcomes related to overdose, addiction, abuse or misuse."[46]

121. A fourth category of deceptive messaging regarding dangerous opioids is the Manufacturer Defendants' false assurances regarding the alleged ease of eliminating opioid dependence. The Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, but they failed to disclose the increased difficulty of stopping opioids after long-term use. In truth, the 2016 CDC Guideline explains that the symptoms of opioid withdrawal include abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia, drug cravings, anxiety, insomnia, spontaneous abortion and premature labor in pregnant women.[47]

122. The Manufacturer Defendants downplayed the severity of opioid detoxification. Upon information and belief, a CME sponsored by Endo, entitled Persistent Pain in the Older Adult, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10% - 20% for 10 days. And Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.[48]

---

[46] *Id.* at 11.

[47] *Id.* at 26.

[48] APF, *Policymaker's Guide*, *supra*, at 32.

123. A fifth category of false, deceptive, and unfair statements the Manufacturer Defendants made to sell more drugs is that opioid dosages could be increased indefinitely without added risk. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. The Manufacturer Defendants' deceptive claims include:

a. Upon information and belief, Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis appears to have continued to use these materials in 2009 and beyond;

b. Cephalon and Non-party co-conspirator Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and insinuated that they are therefore the most appropriate treatment for severe pain.[49] This publication is still available online;

c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain;"

d. Endo distributed a pamphlet edited by a KOL entitled Understanding Your Pain: Taking Oral Opioid Analgesics (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief;"[50]

e. Janssen sponsored a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines

[49] APF, *Treatment Options*, *supra*, at 12.

[50] Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

but omitted any discussion of risks of increased opioid dosages;

f. Upon information and belief, Non-party co-conspirator Purdue's in the Face of Pain website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

g. Non-party co-conspirator Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which taught that dosage escalations are "sometimes necessary," and that "the need for higher doses of medication is not necessarily indicative of addiction," but inaccurately downplayed the risks from high opioid dosages;[51]

h. In 2007, Non-party co-conspirator Purdue sponsored a CME entitled "Overview of Management Options" that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages;

i. Non-party co-conspirator Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," challenging the correlation between opioid dosage and overdose; and[52]

j. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants' Front Groups APF and NFP argued in an amicus brief to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.[53]

124. Once again, the 2016 CDC Guideline reveals that the Manufacturer Defendants' representations regarding opioids were lacking in scientific evidence. The 2016 CDC Guideline clarifies that the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."[54] More

[51] APF, *Policymaker's Guide*, *supra*, at 32.

[52] The College on Problems of Drug Dependence, *About the College*, http://cpdd.org (last visited April 9, 2018).

[53] Brief of APF, *supra*, at 9.

[54] 2016 CDC Guideline, *supra* note 50, at 22–23.

specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."[55] The CDC also states that there is an increased risk "for opioid use disorder, respiratory depression, and death at higher dosages."[56] That is why the CDC advises doctors to "avoid increasing dosage" to above 90 morphine milligram equivalents per day.[57]

125. Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can cure addiction and abuse.

126. The Manufacturer Defendants made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that Opana ER Extended-Release Tablets' "extended- release features can be compromised, causing the medication to 'dose dump,' when subject to . . . forms of manipulation such as cutting, grinding, or chewing, followed by swallowing."[58] Also troubling, Opana ER can be prepared for snorting using commonly available methods and "readily prepared for injection."[59] The letter

---

[55] *Id.* at 23-24.

[56] *Id.* at 21.

[57] *Id.* at 16.

[58] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.

[59] *Id.* at 6.

discussed "the troubling possibility that a higher (and rising) percentage of [Opana ER Extended-Release Tablet] abuse is occurring via injection."[60] Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. In June 2017, the FDA requested that Opana ER be removed from the market.

127. To convince doctors and patients that opioids should be used to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the CDC Guideline makes clear, "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[61] The FDA, too, has recognized the lack of evidence to support long-term opioid use. Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

128. Some illustrative examples of the Manufacturer Defendants' false claims are:

a. Upon information and belief, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives;

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects;

c. Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs;

[60] *Id.* at 6, n. 21.

[61] *Id.* at 15.

d. Janssen promoted Ultracet for everyday chronic pain and distributed posters, for display in doctors' offices, of presumed patients in active professions; the caption read, "Pain doesn't fit into their schedules;

e. Upon information and belief, Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function;

f. Responsible Opioid Prescribing (2007), sponsored and distributed by Cephalon, Endo and Non-party co-conspirator Purdue, taught that relief of pain by opioids, by itself, improved patients' function;

g. Responsible Opioid Prescribing (2007), sponsored and distributed by Cephalon, Endo and Non-party co-conspirator Purdue, taught that relief of pain by opioids, by itself, improved patients' function;

h. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve."[62] This publication is still available online;

i. Endo's NIPC website "PainKnowledge" claimed in 2009, upon information and belief, that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site;

j. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient."[63] Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning;"

k. Janssen sponsored and funded a multimedia patient education campaign called "Let's Talk Pain." One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored website,

[62] APF, *Treatment Options, supra.*

[63] *E.g.*, NIPC, *Persistent Pain and the Older Patient* (2007), https://www.painedu.org/Downloads/NIPC/Activities/B173_Providence_RI_%20Invite.pdf.

part of the "Let's Talk Pain" campaign, featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function;"

l. Non-party co-conspirator Purdue sponsored the development and distribution of APF's A Policymaker's Guide to Understanding Pain & Its Management, which claimed that "[m]ultiple clinical studies" have shown that opioids are effective in improving "[d]aily function," "[p]sychological health," and "[o]verall health-related quality of life for chronic pain."[64] The Policymaker's Guide was originally published in 2011; and

m. Cephalon's, Endo's, Janssen's, and Non-party co-conspirator Purdue's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

129. As the FDA and other agencies have made clear for years, these claims have no support in the scientific literature.

130. In 2010, the FDA warned Actavis, in response to its advertising of Kadian described above, that "we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[65] And in 2008, upon information and belief, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

131. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing medications like NSAIDs, so that doctors and patients would

[64] APF, *Policymaker's Guide*, *supra*, at 29.

[65] Letter from Thomas Abrams to Doug Boothe, *supra* note 32.

look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.[66]

132. Non-party co-conspirator Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action. Upon information and belief, Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, but it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

133. Purdue's competitors were aware of this problem. For example, upon information

[66] 2016 CDC Guideline, *supra*, at 12.

and belief, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Non-party co-conspirator Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Upon information and belief, Purdue's sales representatives continue to tell doctors that OxyContin lasts a full 12 hours. This promoted a culture of

134. Front Groups supported by Non-party co-conspirator Purdue likewise echoed these representations. For example, in an amicus brief submitted to the Supreme Court of Ohio by the American Pain Foundation, the National Foundation for the Treatment of Pain and the Ohio Pain Initiative in support of Purdue, those amici represented:

> OxyContin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow-release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient sleep through the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, OxyContin has been a miracle medication.[67]

135. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora

[67] Reply Brief of Amicus Curiae of the American Pain Foundation, The National Foundation for the Treatment of Pain and the Ohio Pain Initiative Supporting Appellants, *Howland v. Purdue Pharma L.P.*, No. 2003-1538 (Ohio Apr. 13, 2004), 2004 WL 1637768, at *4 (footnote omitted).

should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post- operative pain, or pain due to injury.[68] Specifically, the FDA advised that Fentora "is only approved for breakthrough cancer pain in patients who are opioid-tolerant, meaning those patients who take a regular, daily, around-the-clock narcotic pain medication."[69]

136. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, and for which it is not safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

a. Cephalon paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "[c]linically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain;

b. upon information and belief, Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain; and

c. in December 2011, Cephalon widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for

[68] *See* U.S. Food & Drug Admin., *Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets)* (Sept. 26, 2007), https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm.

[69] *Id.*

"multiple causes of pain" – and not just cancer pain.

137. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

138. Non-party co-conspirator Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the Los Angeles Times, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to act – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report that a Los Angeles clinic prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described it internally as "an organized drug ring" until years after law enforcement shut it down. In doing so, Purdue protected its own profits at the expense of public health and safety.[70]

139. Like Non-party co-conspirator Purdue, Endo has been cited for its failure to set

[70] Harriet Ryan et al., *More Than 1 Million Oxycontin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times, July 10, 2016, http://www.latimes.com/projects/la-me-oxycontin-part2/.

up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

140. As a part of their deceptive marketing scheme, the Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including this State and Plaintiff's Community. For example, the Manufacturer Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs but were less likely to be educated about treating pain and the risks and benefits of opioids, and therefore more likely to accept the Manufacturer Defendants' misrepresentations.

141. The Manufacturer Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. The Manufacturer Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence confirms that elderly patients taking opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance, and a smaller window between safe and unsafe dosages.[71] The 2016 CDC Guideline concludes that there must be "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. *Id.* at 27. The same is true for veterans,

[71] 2016 CDC Guideline, *supra*, at 13.

who are more likely to use anti-anxiety drugs (benzodiazepines) for post- traumatic stress disorder, which interact dangerously with opioids.

142. As alleged herein, the Manufacturer Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts, in the course of manufacturing, marketing, and selling prescription opioids. The Manufacturer Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

143. Defendants Endo, Jansen, Cephalon and Actavis and Non-party co-conspirator Purdue made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

b. creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudo-addiction through their own unbranded publications and on internet sites they operated that were marketed to and accessible by consumers;

d. distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

e. sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudo-addiction, even for high-risk patients;

f. endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

j. endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

l. assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic noncancer pain;

m. creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

n. targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non- cancer pain;

o. targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

p. exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;

q. making deceptive statements concerning the use of opioids to treat chronic noncancer pain to prescribers through in-person detailing; and

r. withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same

prescribers.

144. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience establish that opioids are highly addictive and are responsible for a long list of very serious adverse outcomes. The FDA warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and death – all of which clearly described the harm from long-term opioid use and that patients were suffering from addiction, overdose, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements, based on medical evidence, that conclusively expose the falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements in New York prohibiting them from making some of the same misrepresentations described in this Complaint.

145. At all times relevant to this Complaint, the Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain. Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. The Manufacturer Defendants exerted considerable influence on these promotional and

"educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, PainKnowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Janssen and Non-party co-conspirator Purdue, ran similar websites that masked their own role.

146. The Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful, and supported by objective evidence when they were not. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented "pseudo-addiction" and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. The Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The lack of support for the Manufacturer Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by the Plaintiff or Plaintiff's Community. Thus, the Manufacturer Defendants successfully concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. Plaintiff did not know of the existence or scope of the Manufacturer Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

147. The Distributor Defendants owe a duty under both federal law (21 U.S.C. § 823, 21 CFR 1301.74) and Alabama law (Ala. Code § 20-2-51, et. seq.) to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from the State of Alabama and/or Plaintiff City, as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted into Alabama and/or Plaintiff City. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

148. Each Distributor Defendant repeatedly and purposefully breached its duties under state and federal law. Such breaches are a direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes into the State of Alabama and Plaintiff City.

149. The unlawful diversion of prescription opioids is a direct and proximate cause of the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the State of Alabama and Plaintiff City. This diversion and the epidemic are direct causes of harms for which Plaintiff seeks to recover here.

150. The opioid epidemic in Alabama, including *inter alia* in Plaintiff City, remains an immediate hazard to public health and safety.

151. The opioid epidemic in the Plaintiff City is a public nuisance and remains unabated.

152. The Distributor Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

153. Opioids are a controlled substance and are categorized as "Schedule I" and "Schedule II" drugs under Alabama law. See Ala. Code §§ 20-2-23 and 20-2-25. These drugs are

controlled substances with a "high potential for abuse." 21 U.S.C. §§ 812(b), 812(2)(A)-(C).

154. As wholesale drug distributors, each Distributor Defendant was required under Alabama law to obtain a license as a wholesaler of controlled substances. Ala. Code § 20-2-51

155. Each Distributor Defendant is licensed and registered in Alabama and is a "registrant" or "licensee" as a wholesale distributor in the chain of distribution of Schedule I and Schedule II controlled substances and assumed a duty to comply with all security requirements imposed under the regulations adopted by the State of Alabama.

156. Each Distributor Defendant was further required to register with the DEA, pursuant to the federal Controlled Substance Act. See 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Each Distributor Defendant is a "registrant" as a wholesale distributor in the chain of distribution of Schedule I and Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme.

157. Each Distributor Defendant has an affirmative duty under federal and Alabama law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(b)(1); Ala. Code § 20-2-52.

158. The Alabama State Board of Pharmacy requires that drug wholesalers "shall submit to the Alabama State Board of Pharmacy legible copies of records and reports required by the Drug Enforcement Administration concerning increases in purchases or high or unusual volumes purchased by pharmacies within thirty (30) days." Ala. Code § 680-X-3-.05.

159. Federal regulations, similarly, impose a non-delegable duty upon wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of

controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

160. "Suspicious orders" include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. See 21 CFR 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter, and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of a particular customer but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

161. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. See *Southwood Pharm., Inc.*, 72 Fed. Reg. 36, 487, 36, 501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported. *Id.*

162. These prescription drugs are regulated to provide a "closed" system intended to

reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. See, 1970 U.S.C.C.A.N. 4566, 4571-72.

163. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant's role and responsibilities.[72]

164. As the DEA advised the Distributor Defendants in a letter to them dated September 27, 2006, wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly … distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as … the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[73]

165. The Distributor Defendants have admitted that they are responsible for reporting

[72] Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 [hereinafter Brief for HDMA and NACDS]. The Healthcare Distribution Management Association (HDMA or HMA)-now known as the Healthcare Distribution Alliance (HDA)-is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. *See generally* HDA, *About*, https://www.healthcaredistribution.org/about (last visited Aug. 21, 2017). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, *Mission*, https://www.nacds.org/ about/mission/ (last visited Aug. 21, 2017).

[73] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), *filed in Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

suspicious orders.[74]

166. The DEA sent a letter to each of the Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[75] The letter also instructs that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes."[76] The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[77]

167. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.[78] This letter reminds the Defendants of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[79] The letter further explains:

---

[74] *See* Brief for HDMA and NACDS, *supra* note 85, 2016 WL 1321983, at *4 ("[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).").

[75] Rannazzisi Letter, *supra*, at 2.

[76] *Id.* at 1.

[77] *Id.* at 2.

[78] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv- 00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

[79] *Id.*

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter, and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient.

This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective

> controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC § 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.[80]

168. Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36, 487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[81]

169. The Distributor Defendants admit that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."[82]

170. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to

[80] *Id.*

[81] *Id.*

[82] *See* Brief of HDMA, *supra*, 2012 WL 1637016, at *2.

which the order was otherwise characterized as an order of interest.[83]

171. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in the State of Alabama and/or Plaintiff City and/or to retailers from which Defendants knew prescription opioids were likely to be diverted to the Alabama and/or Plaintiff City.

172. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

173. Each Distributor Defendant owes a duty under federal and state law to investigate and refuse suspicious orders of prescription opioids.

174. Each Distributor Defendant owes a duty under federal and state law to report suspicious orders of prescription opioids.

175. Each Distributor Defendant owes a duty under federal and state law to prevent the diversion of prescription opioids into illicit markets in the State of Alabama and/or Plaintiff City.

176. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction.

177. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality in the Plaintiff City and the damages caused thereby.

178. Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances from

[83] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.[84]

179. The sheer volume of prescription opioids distributed to pharmacies in the Plaintiff's Community, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted into Plaintiff's community, is excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.[85]

180. The Distributor Defendants failed to report "suspicious orders" originating from the State of Alabama and Plaintiff City, or which the Distributor Defendants knew were likely to be diverted to Plaintiff City, to the federal and state authorities, including the DEA and/or the Alabama State Board of Pharmacy.

181. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in the State of Alabama and/or Plaintiff City, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff City.

182. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates originating from the State of Alabama and/or Plaintiff City, and/or in areas from which the Distributor Defendants knew

[84] *See* Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

[85] *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55, 418-01, 55, 482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C.,d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62, 316, 62, 322 (2012)).

opioids were likely to be diverted to the Plaintiff City.

183. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

184. The Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities including the DEA of suspicious orders when discovered, in violation of their duties under federal and state law.

185. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.[86]

186. The federal and state laws at issue here are public safety laws.

187. The Distributor Defendants' violations of public safety statutes constitute prima facie evidence of negligence under State law.

188. The unlawful conduct by the Distributor Defendants is purposeful and intentional.

189. The Distributor Defendants refuse to abide by the duties imposed by federal and state law which are required to legally acquire and maintain a license to distribute prescription opiates.

190. The Distributor Defendants acted with actual malice in breaching their duties, i.e., they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

---

[86] *See Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

191. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

192. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under state and federal law and have wrongfully and repeatedly disavowed those duties to mislead regulators and the public regarding the Distributor Defendants' compliance with their legal duties.

193. Distributor Defendants have refused to recognize any duty beyond reporting suspicious orders. In Masters Pharmaceuticals, the HDMA, a trade association run by the Distributor Defendants, and the NACDS submitted amicus briefs regarding the legal duty of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:

a. The Associations complained that the "DEA has required distributors not only to report suspicious orders, but to investigate orders (e.g., by interrogating pharmacies and physicians) and take action to halt suspicious orders before they are filled;"[87]

b. The Associations argued that, "DEA now appears to have changed its position to require that distributors not only report suspicious orders but investigate and halt suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it is changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications;"[88]

[87] Brief for HDMA and NACDS, *supra*, 2016 WL 1321983, at *4–5.

[88] *Id.* at *8.

c. The Associations alleged (inaccurately) that nothing "requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious;"[89]

d. The Association complained that the purported "practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties;"[90]

e. The Associations alleged (inaccurately) that "DEA's regulations sensibly impose a duty on distributors simply to report suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders;"[91] and

f. Also, inaccurately, the Associations argued that, "[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA's demands."[92]

194. The positions taken by the trade groups is emblematic of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.[93]

195. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Master Pharmaceutical's license and determined that DEA regulations

---

[89] *Id.* at *14.

[90] *Id.* at *22.

[91] *Id.* at *24-25.

[92] *Id.* at *26.

[93] *See* Brief of HDMA, *supra*, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry "does not know the rules of the road because" they claim (inaccurately) that the "DEA has not adequately explained them").

require that in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due diligence' and--if it is able to determine that the order is not likely to be diverted into illegal channels--ship the order." *Id.* at 212. Master Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. *Id.* at 218–19, 226. A distributor's investigation must dispel all the red flags giving rise to suspicious circumstance prior to shipping a suspicious order. *Id.* at 226. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties. *Id.* at 220.

196. Wholesale Distributor McKesson has recently been forced to specifically admit to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[94] Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional

[94] *See* Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), https://www.justice.gov/opa/press-release/file/928476/download.

practice, as required by 21 C.F.R § 1306.04(a)."[95] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 et seq., at the McKesson Distribution Centers."[96] Due to these violations, McKesson agreed that its authority to distribute controlled substances would be partially suspended.[97]

197. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.[98] In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA," but had failed to do so.[99] The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."[100] As a result of these violations, McKesson was fined and required to pay to the United States

[95] *Id.* at 4.

[96] *Id.*

[97] *Id. at 6.*

[98] *Id.* at 4.

[99] *Id.*

[100] *Id.*; *see also* Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter 2017 Settlement Agreement and Release] ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), https://www.justice.gov/opa/press-release/file/928471/download.

$150,000,000.[101]

198. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

199. Because of the Distributor Defendants' refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.[102] The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.[103] These actions include the following:

a. on April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. on November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

[101] *See* 2017 Settlement Agreement and Release, *supra*, at 6.

[102] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

[103] *Id.*

c. on December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. on December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. on January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. on May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. on September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. on February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

i. on December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

j. on January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

200. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[104]

201. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

202. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain and represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[105] Given the

---

[104] *See* Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had No Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

[105] Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* Wash. Post, Oct. 22, 2016,

sales volumes and the company's history of violations, this executive was either not telling the truth, or, if Cardinal Health had such a system, it ignored the results.

203. Similarly, Defendant McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[106] Again, given McKesson's historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

204. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. The Plaintiff did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

205. The opioid epidemic continues unabated in the United States, the State of Alabama and Plaintiff City.

206. The epidemic still continues because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they

---

https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html.

[106] Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from- dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

simply ship from another facility.

207. The wrongful actions and omissions of the Distributor Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in the Plaintiff City's racketeering allegations set forth below.

208. The Distributor Defendants have abandoned their duties imposed under federal and state law, taken advantage of a lack of DEA law enforcement, and abused the privilege of distributing controlled substances in the State of Alabama and Plaintiff City.

209. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Manufacturer Defendants under federal law.

210. Like the Distributor Defendants, the Manufacturer Defendants were required to register with the DEA to manufacture schedule II-controlled substances, like prescription opioids. See 21 U.S.C. § 823(a). A requirement of such registration is the:

> maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes…

21 U.S.C. § 823(a)(1) (emphasis added).

211. Additionally, as "registrants" under Section 823, the Manufacturer Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when

> discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74. *See also* 21 C.F.R. § 1301.02 ("Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter."); 21 C.F.R. § 1300.01 ("Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958)." Like the Distributor Defendants, the Manufacturer Defendants breached these duties.

212. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

213. Federal statutes and regulations are clear: just like opioid distributors, opioid manufacturers are required to "design and operate a system to disclose . . . suspicious orders of controlled substances" and to maintain "effective controls against diversion." 21 C.F.R. § 1301.74; 21 U.S.C. § 823(a)(1).

214. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[107]

215. In the press release accompanying the settlement, the Department of Justice stated: Mallinckrodt did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . . Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . "Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . ."[108]

216. Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[109]

---

[107] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders

[108] *Id.*

[109] *Id.*

217. The Memorandum of Agreement entered into by Mallinckrodt ("2017 Mallinckrodt MOA") avers "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[110]

218. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

219. With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:

a. conduct adequate due diligence of its customers;

b. detect and report to the DEA orders of unusual size and frequency;

c. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:

i. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion;

ii. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products; and

iii. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;

[110] Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download. ("2017 Mallinckrodt MOA").

d. use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

e. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[111]

220. Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007." Mallinckrodt further agreed that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[112]

221. Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to "downstream" registrants." Mallinckrodt agreed that, from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[113]

---

[111] 2017 Mallinckrodt MOA at p. 2-3.

[112] *Id.* at 3-4.

[113] *Id.*

222. The same duties imposed by federal law on Mallinckrodt were imposed upon all Distributor Defendants.

223. The same business practices utilized by Mallinckrodt regarding "charge backs" and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other Distributor Defendants.

224. Through, *inter alia*, the charge back data, the Manufacturer Defendants could monitor suspicious orders of opioids.

225. The Manufacturer Defendants failed to monitor, report, and halt suspicious orders of opioids as required by federal law.

226. The Manufacturer Defendants' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

227. The Manufacturer Defendants misrepresented their compliance with federal law.

228. The wrongful actions and omissions of the Manufacturer Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff's racketeering allegations below.

229. The Manufacturer Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into Plaintiff City.

230. As the Manufacturer Defendants' efforts to expand the market for opioids increased so have the rates of prescription and sale of their products — and the rates of opioid- related substance abuse, hospitalization, and death among the people of the State of Alabama and Plaintiff

City. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids into communities like the Plaintiff's Community, fueling the epidemic.

231. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[114]

232. The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths.[115]

233. Because of the well-established relationship between the use of prescription opiates and the use of non-prescription opioids, like heroin, the large-scale distribution of opioids to the State of Alabama and Plaintiff City and areas from which such opioids are being diverted into Plaintiff's Community, has caused the Defendant-caused opioid epidemic to include heroin addiction, abuse, and death.

234. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in the State and in Plaintiff's Community.

235. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in the State of Alabama and Plaintiff City

236. Defendants repeatedly and purposefully breached their duties under state and federal law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes into the Plaintiff City.

237. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction,

---

[114] *See* Califf et al., *supra.*

[115] *See* Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *supra.*

morbidity and mortality in the State of Alabama and Plaintiff City. This diversion and the epidemic are direct causes of foreseeable harms incurred by the Plaintiff.

238. Defendants intentional and/or unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiff seeks relief, as alleged herein.

239. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

240. These community-based problems require community-based solutions that have been limited by "budgetary constraints at the State and Federal levels."[116]

241. Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opiates, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon the Plaintiff and Plaintiff's Community.

242. Plaintiff contends it continues to suffer harm from the unlawful actions by the Defendants.

243. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated.

244. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State of Alabama and Plaintiff City, that they were

[116] *See* Office of Nat'l Drug Control Policy, Exec. Office of the President, *Epidemic: Responding to America's Prescription Drug Abuse Crisis* (2011), https://www.ncjrs.gov/pdffiles1/ondcp/rx_abuse_plan.pdf.

undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the State of Alabama and Plaintiff City, that they are working to curb the opioid epidemic.

245. The Distributor Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, that will confirm their identities and the extent of their wrongful and illegal activities.

246. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented "pseudo-addiction" and promoted it to an unsuspecting medical community. Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The medical community, consumers, the State of Alabama and Plaintiff City were duped by the Manufacturer Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the Alabama and Plaintiff City.

247. Plaintiff City reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

248. The Plaintiff's claims are further subject to equitable tolling, stemming from Defendants' knowingly and fraudulently concealing the facts alleged herein. As alleged herein,

Defendants knew of the wrongful acts set forth above, and had material information pertinent to their discovery, and concealed them from the Plaintiff. The Plaintiff did not know or could not have known through the exercise of reasonable diligence, of its cause of action, as a result of Defendants' conduct.

249. The purposes of the statutes of limitations period are satisfied because Defendants cannot claim prejudice due to a late filing where the Plaintiff filed suit promptly upon discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

250. In light of their statements to the media, in legal filings, and settlements, it is clear that Defendants had actual or constructive knowledge that their conduct was deceptive, in that they consciously concealed the schemes set forth herein.

251. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. As a result of the above, the Plaintiff was unable to obtain vital information bearing on its claims absent any fault or lack of diligence on its part.

V. CAUSES OF ACTION

COUNT I
NEGLIGENCE

The Plaintiff incorporates Paragraphs 1 through 250 as if fully restated and set forth herein.

251. The Defendants owe a duty to use reasonable care to prevent causing harm to the Plaintiff resulting from the Defendants' marketing, distribution, delivery, and sale of prescription opioids in the State of Alabama and particularly in the Plaintiff City.

252. The Defendants also owe a duty to the Plaintiff to maintain all appropriate licensing in Alabama to distribute prescription opioids, to investigate and report on improper, suspicious and illegal orders, and to prevent and stop any and all illegitimate shipments and distributions of opioids into this State.

253. The Defendants are further under a legal duty to protect the health and welfare of the citizens of Alabama by following federal and state laws concerning misuse and abuse of controlled substances.[117]

254. Rather than uphold and follow their duties as set forth above, imposed by statute and at common law, the Defendants, individually and collectively, worked to breach their duties, both directly and by subterfuge, artifice and deception. The Defendants' breach of duty in many cases is willful, reckless, wanton and in total disregard of the safety of the public.

255. As a result of the Defendants' breach of their legal duties, Alabama suffers the highest rate of prescription opioid usage in America at an astonishing rate of 142.9 prescriptions per 100 people. Prescription rates of benzodiazepine and other synthetic opioids are at equally high rates in Alabama.

256. The volume of prescription opioids written, sold, shipped and delivered by Defendants to the State of Alabama and Plaintiff City is beyond the amount that a reasonably prudent corporate entity would provide under similar circumstances given the applicable regulations and knowledge available to the Defendants.

[117] Ala. Code §§ 20-2-52, § 20-2-56, § 20-2-57, and Alabama Administrative Code §§ 680-X-3.05, § 680-X-2-.23(k)(3), and laws incorporated therein, including federal controlled substance laws, which are public safety laws. The Alabama Legislature has found that "the division, abuse, and misuse of prescription medications classified as controlled substances under the Alabama Uniform Controlled Substances Act constitutes a serious threat to the health and welfare of the citizens of the State of Alabama." ALA. CODE § 20-2-210.

257. The Defendants' marketing and promotion of their opioid prescription drug products is inconsistent and contrary to the actions of reasonably prudent corporate entities under similar circumstances given the applicable knowledge and information of the Defendants that they have created an opioid drug crisis across America, the State of Alabama and Plaintiff City. Instead of exercising caution, issuing reports to federal, state and local governments about out-of-control opioid distribution and use, the Defendants actively worked to sell and distribute more prescription opioids without regard for the consequences and damages being caused to the Plaintiff.

258. The Defendants know that there is a strong connection between abuse of prescription opioids and the use of heroin. The strongest and most direct indicator of heroin usage is introduction to, and abuse of, prescription opioids. Government studies have linked the use and abuse of prescription painkillers to the growing use of heroin and the resulting occurrence of overdoes and deaths from heroin.

259. Defendants' conduct fell below the reasonable standard of care and was negligent. Their negligent acts include:

a. Consciously supplying the market of Plaintiff City with highly addictive prescription opioids, including misrepresenting, understating, or obfuscating the highly addictive propensities of opioid pills;

b. Using unsafe marketing, labeling, distribution, and dispensing practices, including failing to warn or advise physicians to conduct an addiction family history of each potential patient;

c. Affirmatively enhancing the risk of harm from prescription opioids by failing to act as a last line of defense against diversion;

d. Failing to properly train or investigate their employees;

e. Failing to properly review and analyze prescription orders and data for red flags;

f. Failing to report suspicious orders or refuse to fill them;

g. Failing to provide effective controls and procedures to detect and/or guard against theft and diversion of controlled substances;

h. Failing to police the integrity of their supply chains; and

i. Creating misleading information with the intention of having prescribing physicians rely upon it.

260. Defendants sold prescription opioids in the supply chain knowing (a) there was a substantial likelihood many of the sales were for non-medical purposes and, (b) opioids are an inherently dangerous product when used for non-medical purposes, and (c) that every patient, before being prescribed even one opioid pill, needed to have a complete family history of addiction to alcohol and drugs, with any such history as a contraindication of any opioid use.

261. Defendants' breach of duty and failure to use reasonable care in the distribution, investigation, reporting, marketing, delivery and sale of prescription opioids have led to the resulting heroin abuse and addiction experienced by the citizens of the Plaintiff City, in addition to the illegal distribution of prescription opioids in the Plaintiff City.

262. As a result of the Defendants' breach of duty and failure to use reasonable care, the Plaintiff has been and continues to be damaged through the rampant distribution of prescription opioids that the Defendants were under a duty to monitor and control, but instead enabled, expanded and participated in the wrongful distribution of their products.

263. As a proximate result of the Defendants' conduct, the Plaintiff has been damaged, and will continue to be damaged, and seek all legal and equitable relief as allowed by law,

including, *inter alia*, actual damages, compensatory damages, punitive damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorneys' fees and all costs and expenses of suit and pre- and post-judgment in

COUNT II
FRAUD AND MISREPRESENTATION

The Plaintiff incorporates Paragraphs 1 through 263 as if fully restated and set forth herein.

264. This Count is brought pursuant to Alabama Code §§ 6-5-101 to 6-5-104 (1975).

265. The Defendants have separately and severally committed misrepresentation, deceit, concealment and fraud. The Defendants have separately and severally committed fraud and misrepresentation through:

- the willful, reckless or mistaken representations of materials facts;
- the suppression of material facts that Defendants were under a duty to communicate;
- the concealment of material facts with the intent to deceive and mislead;
- the misrepresentation of material facts made willfully to induce actions to the Plaintiff's detriment; and
- the intentional misrepresentation of material facts with knowledge of the falsity of the representations with intent the Plaintiff would rely on the representations to their detriment.

266. In an effort to mislead the public concerning risks, benefits and safety of prescription opioids, the Defendants worked both individually and in concert to deceptively market and falsely present their products.

267. Similarly, to the deceptions inflicted on the American public by the tobacco companies denying the addictive nature of smoking and the serious adverse health effects caused by smoking, the Defendants have worked in concert to minimize the addictive aspects of opioids and the serious adverse consequences of using prescription opioids.

268. Through their actions and marketing efforts to the public, patients and healthcare professionals, including hospitals, doctors and nurses, the Defendants spent millions of dollars to conduct a campaign of fraudulent misrepresentations, including, *to wit*:

- misrepresenting and misleading the truth about opioids and addiction;
- misrepresenting that opioids improve function;
- misrepresenting that opioid dependency can be managed;
- misrepresenting that opioid prescriptions create dependency leading to illegal street drugs;
- misrepresenting that opioids should be used for very short periods of time and not for chronic pain;
- misrepresenting that Defendants had funded alleged "independent research" to support their misrepresentations and fraudulent claims concerning the effectiveness of opioid derivatives to prevent or minimize addiction risks;
- misrepresenting that opioid withdrawal could be easily and simply managed;
- falsely and fraudulently stating that opioid dosage posed no significant risks to patients; and
- falsely and fraudulently suppressing the serious adverse effects of opioids while overstating the risks and potential complications from use of alternative forms of pain treatment.

269. Defendants' fraud and misrepresentation has exacted a financial burden for which the Plaintiff seeks relief and damages. As a proximate result of the Defendants' conduct, the Plaintiff has been damaged, and will continue to be damaged, and seek all legal and equitable relief as allowed by law, including, *inter alia*, actual damages, compensatory damages, punitive damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorneys' fees and all costs and expenses of suit and pre- and post-judgment interest.

COUNT III
NUISANCE

The Plaintiff incorporates Paragraphs 1 through 269 as if fully restated and set forth herein.

270. Plaintiff City has standing to pursue nuisance claims against the Defendants for public nuisance pursuant to Ala. Code § 6-5-121 (1975).

271. Plaintiff City has standing to pursue nuisance claims against the Defendants for public nuisance pursuant to Ala. Code § 11-1-2 (1975).

272. Citizens of Plaintiff City have the right to be protected from dangers to the public health, safety and welfare resulting from a public nuisance.

273. Pursuant to Alabama law, a nuisance includes "anything that works, hurt, inconvenience or damage to another" and a public nuisance is defined as anything "which damages all persons who come within the spear of its operation, though it may vary in its effects on individuals." Ala. Code § 6-5-121 and 122 (1975).

274. The Defendants, individually as well as acting through their agents, and in concert with one another, have created an opioid epidemic that has created harm, damage and inconvenience to the Plaintiff and its residents. Although the effects of the nuisance created by the Defendants may vary on individuals within Plaintiff City, the Defendants have created a nuisance, and damaged the public by engaging in the following conduct, *to wit*:

- creating, financing and supporting the distribution of patient and prescriber education materials misrepresenting data concerning the safety efficacy of opioids for long-term treatment of chronic non-cancer pain, including the known rates of abuse and addiction and the lack of validation of the same for long-term efficacy;

- developing and disseminating misleading scientific studies concluding the safety of opioids for long-term treatment of chronic non-cancer pain;

- developing and disseminating misleading scientific studies based on incomplete or inadequate data while concealing facts about the danger of prescription opioids;

- sponsoring, distributing and assisting in the distribution of publications presenting an unbalanced presentation of the long-term dose and dependent risks of opioids versus alternatives;

- creating, sponsoring and distributing patient education materials to consumers containing deceptive statements about opioid use;

- marketing opioid drugs as safe and effective for long-term treatment of chronic pain conditions when they were not safe, for the purpose of deceiving physicians into using and prescribing addictive opioid drugs to their patients;

- distributing brochures to doctors, patients and law enforcement officials that included statements concerning the indicators of possible opioid abuse;

- disseminating misleading statements regarding the true risk of addiction and promoting the concept of pseudo-addiction through Defendants' own unbranded publications on internet sites, operated by the Defendants, directed to care givers, consumers, and healthcare professionals;

- acting intentionally, recklessly, and unlawfully in failing to maintain controls against prescription opioid diversion through monitoring, reporting and in recognition of the Defendants' duty to refuse to fill suspicious orders of opioids;

- by refusing to fill suspicious and unwarranted orders of prescription opioids in order to maintain effective controls against drug diversion and unlawfully continuing the ship prescription opioids to Plaintiff City; and

- marketing, distributing, and selling prescription opioids which the Defendants knew, or should have known, were being diverted for non-legitimate, non-medical use, with a substantial likelihood of illegal and improper distribution to the public.

275. The Defendants' actions are continuing in nature and as a result of said actions, the Defendants have negatively impacted the rights of the citizens of Plaintiff City to live without unreasonable interference to the public health, safety, welfare, peace, comfort and convenience, unreasonable threat of crime, and the right to be free from disturbance without the unreasonable apprehension of danger to personal property resulting from the opioid epidemic.

276. The Defendants' actions, separate and severally, have been, and continue to be, a substantial factor in opioids becoming widely available and widely used for non-medical purposes. The Defendants, separately and severally, have a responsibility, and legal obligation, within the system of opioid distribution to refrain from conduct that would create a widespread nuisance which negatively affects Plaintiff City, creating an enormous public health crisis resulting from the overuse of prescription opioids and heroin.

277. The Defendants' conduct is a direct and proximate cause of death, injury, and damage to the citizens of Plaintiff City, which has caused financial damage to Plaintiff, and if allowed to continue, unabated, will continue to threaten the health, safety and welfare of Plaintiff City.

278. The Defendants' conduct is ongoing and persistent, and the Plaintiff seeks to recover all damages flowing from the Defendants' conduct, including abatement of the nuisance and all harm created by the Defendants' conduct, as well as all legal and equitable relief as allowed by law, including, *inter alia*, actual damages, compensatory damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorneys' fees and all costs and expenses of suit and pre- and post-judgment interest.

279. In addition to the compensatory damages sought above for actual damages and abatement damages, Plaintiff claims the right to be compensated in punitive damages against the Defendants as a result of their deliberate and intentional actions committed with malice and oppression and with knowledge that their actions would likely result in grave harm.

COUNT IV
DRUG NUISANCE
ALABAMA STATUTE § 6-5-155 *et seq*.

The Plaintiff incorporates Paragraphs 1 through 279 as if fully restated and set forth herein.

280. It cannot be denied there is an opioid epidemic in America and the epidemic has resulted in increased financial costs to hospitals to address public health issues.

281. As stated herein, the Defendants' actions in the marketing, presentation, representation, distribution, advertising, and sale of prescription opioids have created consumption of opioid related drugs that has become dangerous and harmful to the public welfare. Prescription

opioid abuse has led to increased crime and criminal activity in the State of Alabama and Plaintiff City.

282. In Plaintiff City, the nationwide opioid epidemic has been especially damaging, impacting people from all walks of life from newborns to the elderly, including all races and socio-economic levels of the population. By their conduct, the Defendants have created a drug related nuisance in Plaintiff City.[118]

283. Alabama recognizes that drugs can have a tremendous negative impact on communities, such as Plaintiff City. The Alabama Code defines a "Drug-Related Nuisance" as the "sale, distribution, possession, storage, transportation or manufacture of any controlled substance in violation of the controlled substances acts, or similar act of the United States or any other state" that causes harm to a community. Ala. Code § 6-5-155.

284. There is a duty and corresponding right provided under Alabama law for any person to take action against drug related nuisances to "file an action in the circuit courts of this state to abate, enjoin, and prevent the drug-related nuisance." Ala. Code § 6-5-155(2).

285. The Alabama Uniform Controlled Substance Act, the U.S. Controlled Substances Act and regulations promulgated by the Alabama State Board of Pharmacy proscribe Defendants' manufacture and distribution of opioids while failing to maintain effective controls against diversion. *See, e.g.*, 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(a)(1), (b)(1); ALA. CODE §§ 20-2-56 and 57; ALA. ADMIN. CODE §680-X-3-.05. This manufacture and distribution in violation of the controlled substance acts or similar act of the United States constitutes a Drug-Related

[118] For purposes of the Drug-Related Nuisance statute, "controlled substance acts" are defined as "[t]he provisions of Sections 20-2-1 et seq., known as the "Alabama Uniform Controlled Substance Act," and Sections 13A-12-201 et seq., known as "The Drug Predator Control Act of 1987," and Sections 13A-12-210 et seq., known as "The Drug Crimes Amendments Act of 1987." ALA. CODE § 6-5-155.1.

Nuisance. As a result of the drug-related nuisance created by the Defendants, and as elaborated in the preceding paragraphs, Plaintiff City has sustained damages, harm and unreasonable jeopardy to the health, morals, comfort, welfare, and safety of their communities and to their residents.

286. The Defendants' conduct is ongoing and persistent, and the Plaintiff seeks to recover all damages flowing from the Defendants' conduct, including abatement of the nuisance and all harm created by the Defendants' conduct, as well as all legal and equitable relief as allowed by law, including, *inter alia*, actual damages, compensatory damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorneys' fees, all costs and expenses of suit, pre- and post-judgment interest and daily statutory fines as provided under Alabama law. See Ala. Code § 6-5-155.7.

287. In addition to the compensatory and statutory damages sought above for actual damages and abatement costs, Plaintiff claims the right to be compensated in punitive damages against the Defendants as a result of their deliberate and intentional actions committed with malice and oppression and with knowledge that their actions would likely result in grave harm.

COUNT V
CIVIL CONSPIRACY

The Plaintiff incorporates Paragraphs 1 through 287 as if fully restated and set forth herein.

288. Alabama law recognizes a civil conspiracy cause of action where multiple parties act in concert to commit wrongful acts. The Defendants have in the past, and continue through the present, to work in a concerted effort to profit from the sale of prescription opioid drugs through violations of their statutory duties under the Controlled Substances Act, 21 U.S.C. § 801(2), 21 U.S.C. § 821-824 and 21 U.S.C. § 823(6)(1).

289. The Defendants, separately and severally, encouraged their wholesalers and pharmacists to purchase ever increasing amounts of prescription opioids, and to increase their sales

volume, by providing them discounts and rebates based upon market share and sales volume. The Defendants worked in concert to incentivize purchases of wholesale prescription opioid drugs so that they could decrease their costs per pill and increase their profits. By decreasing volume purchase prices to high volume distributors and pharmacies, the Defendants' distributors could maintain prescription opioid drug costs while increasing their profits.

290. The Defendants, working clandestinely, incentivized their distributors and pharmacies to boost opioid sales through a series of contractual relationships allowing for the coordination of sales activities, incentives and increased profits.

291. As a result of the Defendants' conspiratorial activities and incentives, the sales volume of prescription opioids increased dramatically, along with revenues, with a corresponding increase of illegitimate, improper, and illegal prescription opioids being distributed to the public.

292. Under constant pressure from Defendants to increase sales, wholesale distributors and pharmacies were directed to sell more opioids, fill more "borderline" or suspicious orders, and increase distribution amounts of opioid based prescription drugs to the point that it was obvious to those taking part in the conspiracy that a large amount of the prescription drug sales could not possibly be legitimate, that there could not be any legitimate medical justification for the skyrocketing opioid sales, and that opioid distribution was exponentially exceeding reasonable limits.

293. Defendants' statutory duties of reporting unusual sales, suspect transactions and unlawful diversion of dangerous controlled substances, were (and are) being ignored. The Defendants and their distributors were on notice from the United States Government that repeated DEA enforcement actions were being conducted in the State of Alabama, and that a vast amount of prescription opioids was being abused and diverted in the State of Alabama, and the Defendants'

legal obligations to maintain "effective controls" to prevent the illegal sale and distribution of prescription opioid drugs were being ignored and overlooked.

294. Ignoring their legal and statutory duties, the Defendants not only disregarded danger signs, but advanced policies and procedures to cover up their illegal (but highly profitable) conduct in a conspiracy to sell more prescription opioids. In disregard of the facts indicating an opioid epidemic, the Defendants have continued their "aggressive marketing" practices.

295. To justify the alarming number of opioids distributed across America and within Alabama, the Defendants advanced their conspiracy through the misrepresentation of their products including the public's need for opioids and the lack of legitimate reasons for skyrocketing consumption numbers, including, *to wit*:

- misrepresenting and misleading the truth behind increasing sales and opioid addiction;
- misrepresenting that opioids improve patient function;
- misrepresenting that opioid dependency can be effectively managed;
- misrepresenting that opioid prescriptions create dependency leading to illegal street drug consumption;
- misrepresenting that opioids should be used for very short periods of time and not for chronic pain;
- misrepresenting that Defendants had funded alleged "independent research" to support their misrepresentations and fraudulent claims concerning the effectiveness of opioid derivatives to prevent or minimize addiction risks;
- misrepresenting that opioid withdrawal could be easily and simply managed;
- falsely and fraudulently stating that opioid dosage posed no significant risks to patients; and
- falsely and fraudulently suppressing the serious adverse effects of opioids while overstating the risks and potential complications from use of alternative forms of pain treatment.

296. Defendants' conspiracy has exacted a financial burden for which the Plaintiff seeks relief and damages. As a proximate result of the Defendants' conduct, the Plaintiff has been

damaged, and will continue to be damaged, and seek all legal and equitable relief as allowed by law, including, *inter alia*, actual damages, compensatory damages, punitive damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorneys' fees and all costs and expenses of suit and pre- and post-judgment interest.

COUNT VI
WANTON-INTENTIONAL CONDUCT
PUNITIVE DAMAGES

The Plaintiff incorporates Paragraphs 1 through 296 as if fully restated and set forth herein.

297. The Defendants' actions, separately and severally, are the product of their conscious disregard of the rights and safety of the citizens of Plaintiff City, with the attendant awareness that harm will (and has) likely result from the Defendants' actions.

298. The actions of the Defendants are set forth in the preceding counts and paragraphs of this Complaint and are incorporated herein by reference. The Defendants' actions are willful, wanton, intentional and committed with reckless disregard for the rights and safety of the citizens of Plaintiff City.

299. The conduct of the Defendants has been, and continues to be, willful as defined by Alabama law such that Defendants were aware that their actions, as well as their failure to act in stopping and preventing improper opioid distribution, would cause harm to the public.

300. While the Defendants may not have intended harm to the specific named Plaintiff in this case, the Defendants knew their breach of their legal duties would cause great harm to the American public and Alabamians in particular, yet they proceeded in their efforts to distribute and sell prescription opioids in disregard of the rights and safety of the citizens of Plaintiff City.

301. The actions of the Defendants, separately and severally, have combined and concurred to harm Plaintiff City, and the actions of the Defendants have all contributed to cause the Plaintiff's damages.

302. The actions of the Defendants have, and continue to be, carried on with a reckless and/or conscious disregard for the rights, welfare and safety of the citizens of Plaintiff City.

303. The actions of the Defendants have, and continue to be, the source of unjust hardship to the citizens of Plaintiff City.

304. The actions of the Defendants have, and continue to be, wrongful actions without just cause or excuse.

305. The Plaintiff demands judgment from the Defendants in an amount of money sufficient to punish the Defendants for their wrongful conduct and to protect the public by deterring and discouraging the Defendants and others from doing the same or similar wrongs in the future.

COUNT IV
RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ACT
"RICO" 18 U.S.C. 1961, *et seq*.

The Plaintiff incorporates Paragraphs 1 through 305 as if fully restated and set forth herein.

306. Plaintiff brings this RICO Count against all Defendants.

307. The RICO Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, the RICO Defendants were "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

308. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign

commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C. § 1962(c); *United States v. Turkette*, 452 U.S. 576, 580 (1981).

309. The term "enterprise" includes "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4); *Turkette*, 452 U.S. at 580; *Boyle v. U.S.*, 556 U.S. 938, 944 (2009). The definition of "enterprise" in Section 1961(4) includes legitimate and illegitimate enterprises within its scope.

310. The RICO Defendants aggressively sought to build their revenue, increase profit and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the RICO Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As "registrants," the RICO Defendants operated and continue to operate within the "closed system" created under the Controlled Substances Act, 21 U.S.C. § 821, *et seq.* (the "CSA"). The CSA restricts the RICO Defendants' ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

311. The Opioid Diversion Enterprise (as defined below) systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful

sales of suspicious orders and to notify the DEA of suspicious orders.[3] The RICO Defendants placed hundreds of millions of pills into the illicit market, which allowed them to generate obscene profits, by the unlawful sales of opioids.

312. Each of the RICO Defendants were associated with and conducted or participated in the affairs of the RICO enterprise (defined below and referred to collectively as the "Opioid Diversion Enterprise"), the purpose of which was to engage in the unlawful sales of opioids, while deceiving the public and federal and state regulators into believing that the RICO Defendants were fulfilling their statutory obligations. As a direct result of the RICO Defendants' fraudulent scheme, course of conduct and pattern of racketeering activity, they were able to extract billions of dollars of revenue from the American public. The RICO Defendants' misconduct violated Section 1962(c), and 18 U.S.C. § 1964(c) entitles Plaintiff to treble damages for its injuries.

313. The RICO Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. The Healthcare Distribution Alliance (the "HDA") is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity.

314. Each of the RICO Defendants is a legal entity separate and distinct from the HDA. Additionally, the HDA serves the interests of distributors and manufacturers beyond the RICO Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each

[3] 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).

of the RICO Defendants exists separately from the HDA. Therefore, the HDA may serve as a RICO enterprise.

315. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the RICO Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the "Opioid Diversion Enterprise."

A. THE OPIOID DIVERSION ENTERPRISE

316. The United States Congress enacted the Controlled Substances Act in 1970.[119] The CSA and its implementing regulations created a closed system of distribution for all controlled substances. The closed chain of distribution was intended to prevent the diversion of legally produced controlled substances into the illicit market. Congress specifically designed the closed system to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain. All registrants – manufacturers and distributors alike – must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion. When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse. The result is the scourge of addiction that has occurred.

317. The closed system created by the CSA required the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities

[119] Joseph T. Rannazzisi Decl. ¶ 4, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

of the basic ingredients needed for the manufacture of [controlled substances] and requiring order forms for all transfers of these drugs." The DEA published suggested questions that a distributor should ask prior to shipping controlled substances, in order to "know their customers."

318. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA or (2) in excess of a quota assigned to it by the DEA.

319. At all relevant times, the RICO Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by disregarding their statutory duty to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.[120]

320. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which the RICO Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Defendants; (d) was characterized by interpersonal relationships among the RICO Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. *Turkette*,

[120] The opioid epidemic has its origins in the mid-1990s when, between 1997 and 2007, per capita purchase of methadone, hydrocodone and oxycodone increased 13-fold, 4-fold and 9-fold, respectively. By 2010, enough prescription opioids were sold in the United States to medicate every adult in the country with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month. Am J Public Health 2014; 104(2):e52-9.

452 U.S. at 580; *Boyle*, 556 U.S. at 944 (2009). Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the Opioid Diversion Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and requests that the DEA increase production quotas, all so that the RICO Defendants would have a larger pool of prescription opioids from which to profit.

321. The Opioid Diversion Enterprise functioned by selling prescription opioids. The RICO Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity that involves a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids and the identification, investigation and reporting of suspicious orders of prescription opioids destined for the illicit drug market.

322. The Opioid Diversion Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across state lines, such as manufacture, sale, distribution and shipment of prescription opioids throughout the country and this jurisdiction and the corresponding payment and/or receipt of money from the sale of the same.

323. The Opioid Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity. Each of the RICO Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The RICO Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein.

324. The Healthcare Distribution Alliance ("HDA") led to the formation of interpersonal relationships and an organization between the RICO Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants named in the Complaint, were members of the HDA.174 Additionally, the HDA and each of the Distributor Defendants eagerly sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

325. The HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners" and "make connections." The HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturers and Defendants.

326. There are two types of memberships in the HDA; manufacturer and distributor. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the RICO Defendants. A "senior company executive" must sign the manufacturer membership application, and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year-end net sales through any HDA distributors. After becoming members, the Distributors and

Manufacturers were eligible to participate on councils, committees, task forces and working groups.

327. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise's organization. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues." The conferences also gave the Manufacturer and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."

328. The RICO Defendants maintained their interpersonal relationships by working together, exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

329. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids. As reported in the Washington Post, identified by Senator McCaskill and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturers paid the Distributors rebates and/or chargebacks on their prescription opioid sales. On information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices. The

Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

330. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The RICO Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the Pain Care Forum are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the RICO Defendants were in communication and cooperation.

331. The RICO Defendants began working together as early as 2006 through the Pain Care Forum and/or the HDA to promote the common purpose of their enterprise. Plaintiff is informed and believes that the RICO Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

332. From 2006 to 2016, the Distributors and Manufacturers worked together through the Pain Care Forum to spend over $740 million lobbying in the nation's capital and in all 50 statehouses on issues including opioid-related measures. Similarly, the HDA has continued its work on behalf of Distributors and Manufacturers, without interruption, since at least 2000, if not longer.

B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE

333. During the time period alleged in this Complaint, the RICO Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate and report

suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market and to halt such unlawful sales so as to increase production quotas and generate unlawful profits, as follows:

334. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

335. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.

336. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

337. Defendants paid nearly $800 million dollars to influence local, state and federal governments through joint lobbying efforts as part of the Pain Care Forum. The RICO Defendants were all members of their Pain Care Forum either directly or indirectly through the HDA. The lobbying efforts of the Pain Care Forum and its members included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

338. The RICO Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

339. The RICO Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied

Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act.

340. The RICO Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. Plaintiff is informed and believes that the Manufacturer Defendants used the chargeback program to acquire detailed, high-level data regarding sales of the opioids they manufactured. Additionally, Plaintiff is informed and believes that the Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

341. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas year after year by submitting net disposal information that the Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids the RICO Defendants had not properly investigated or reported.

342. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help the RICO Defendants identify suspicious orders or customers who were likely to divert prescription opioids. On information and belief, the "know your customer" questionnaires informed the RICO Defendants of the number of pills that the pharmacies sold, how many non-controlled substances they sold compared to controlled substances, whether the pharmacy buys from other distributors, and the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

343. The RICO Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion

rings. The RICO Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012 and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders -- all for failure to report suspicious orders.

344. Defendants' scheme had a decision-making structure driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the State and Federal Government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion and identify suspicious orders and report them to the DEA.

345. The RICO Defendants worked together to control the flow of information and influence state and federal governments and political candidates to pass legislation that was pro-opioid. The Manufacturer and Distributor Defendants did this through their participation in the Pain Care Forum and Healthcare Distributors Alliance.

346. The RICO Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, the RICO Defendants ensured that the DEA had no basis for refusing to increase or decrease the production quotas for prescription opioids due to diversion of suspicious orders.

347. The scheme the RICO Defendants devised and implemented amounted to a common course of conduct characterized by a refusal to maintain effective controls against

diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

C. PATTERN OF RACKETEERING ACTIVITY

348. The RICO Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343) and (18 U.S.C. § 1961(D)) by the felonious manufacture, importation, receiving, concealment, buying, selling or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

1. The RICO Defendants Engaged in Mail and Wire Fraud

349. The RICO Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators and the American public by knowingly conducting or participating in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

350. The RICO Defendants committed, conspired to commit and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Defendants' regular use of the facilities, services, distribution channels and employees of the Opioid Diversion

Enterprise. The RICO Defendants participated in the scheme to defraud by using mail, telephone and the internet to transmit mailings and wires in interstate or foreign commerce.

351. The RICO Defendants used, directed the use of and/or caused to be used thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

352. In devising and executing the illegal scheme, the RICO Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises or omissions of material facts. For the purpose of executing the illegal scheme, the RICO Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

353. The RICO Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market and sell the prescription opioids by means of false pretenses, misrepresentations, promises and omissions.

b. Wire Fraud: The RICO Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market and sell the prescription opioids by means of false pretenses, misrepresentations, promises and omissions.

354. The RICO Defendants' use of the mail and wires includes, but is not limited to, Manufacturers, Distributors or third parties that were foreseeably caused to conduct the transmission, delivery or shipment of the following as a result of the RICO Defendants' illegal scheme, including but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;

c. Defendants' DEA registrations;

d. Documents and communications that supported and/or facilitated Defendants' DEA registrations;

e. Documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas and procurement quotas;

f. Defendants' records and reports that 21 U.S.C. § 827 required Defendants to submit to the DEA;

g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributors to the Manufacturers;

k. Rebates and chargebacks from the Manufacturers to the Distributors;

l. Payments to Defendants' lobbyists through the Pain Care Forum;

m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

355. On information and belief, the RICO Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

356. The RICO Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

357. Plaintiff is also informed and believes that the RICO Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales and to transmit payments and rebates/chargebacks.

358. The RICO Defendants also communicated by U.S. Mail, by interstate facsimile and by interstate electronic mail with each other and various other affiliates, regional offices, regulators, distributors and other third-party entities in furtherance of the scheme.

359. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids, all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Defendants intended their scheme and common course of conduct to increase or maintain high production quotas for their prescription opioids from which they could profit.

360. Defendants have deliberately hidden many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities, and these cannot be alleged without access to Defendants' books and records. However, Plaintiff has described the types of and, in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

361. The Defendants and Non-party co-conspirators, for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by interstate carrier, shipments of prescription opioids affecting interstate commerce, including the following:

Please see Chart on Next Page

Defendant Group Name	Company Name	Drugs		
		Drug Name	**Chemical Name**	**CSA Schedule**
Cephalon	**(1)** Cephalon, Inc., **(2)** Teva Pharmaceutical Industries, Ltd, **(3)** Teva Pharmaceuticals USA, Inc.	Actiq	Fentanyl Citrate	Schedule II
		Fentora	Fentanyl Citrate	Schedule II
		Generic Oxycontin	Oxycodone HCl	Schedule II
Janssen	**(1)** Johnson & Johnson; **(2)** Janssen Pharmaceuticals, Inc. (formerly (2a) *Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, formerly (2b) *Janssen Pharmaceutica, Inc.* **(3)** Noramco, Inc.	Duragesic	Fentanyl	Schedule II
		Nucynta	Tapentadol	Schedule II
		Nucynta ER	Tapentadol ER	Schedule II
Endo	**(1)** Endo Health Solutions Inc., **(2)** Endo Pharmaceuticals Inc., **(3)** Qualitest Pharmaceuticals, Inc.	Opana ER	Oxymorphone HCl ER	Schedule II
		Opana	Oxymorphone HCl	Schedule II
		Percodan	Oxymorphone HCl and Aspirin	Schedule II
		Percocet	Oxymorphone HCl and Acetaminophen	Schedule II
		Zydone	Hydrocodone Bitartrate and Acetaminophen	Schedule III
Actavis	**(1)** Allergan Plc **(2)** Actavis LLC, **(3)** Actavis Pharma, Inc., **(4)** Actavis Plc, **(5)** Actavis, Inc., **(6)** Watson Pharmaceuticals, Inc., **(7)** Watson Laboratories, Inc., **(8)** Watson Pharma, Inc.	Kadian	Morphine Sulfate	Schedule II
		Norco	Hydrocodone and Acetaminophen	Schedule II
Actavis	**(1)** Allergan Plc **(2)** Actavis LLC, **(3)** Actavis Pharma, Inc., **(4)** Actavis Plc, **(5)** Actavis, Inc., **(6)** Watson Pharmaceuticals, Inc., **(7)** Watson Laboratories, Inc., **(8)** Watson Pharma, Inc.	Generic Duragesic	Fentanyl	Schedule II
		Generic Opana	Oxymorphone HCl	Schedule II

Non-Party Co-Conspirators who contributed but are not named, include:

Insys	Insys Therapeutics, Inc.	Subsys	Fentanyl	Schedule II
Mallinckrodt	**(1)** Mallinckrodt PLC, **(2)** Mallinckrodt, LLC	Exalgo	Hydromorphone HCl	Schedule II
Purdue	**(1)** Purdue Pharma, LP, **(2)** Purdue Pharma, Inc., **(3)** The Purdue Frederick Company	OxyContin	Oxycodone HCL ER	Schedule II
		MS Contin	Morphine Sulfate ER	Schedule II
		Dilaudid	Hydromorphone HCl	Schedule II
		Dilaudid-HP	Hydromorphone HCl	Schedule II
		Butrans	Buprenorphine	Schedule III
		Hysingla ER	Hydrocodone Bitrate	Schedule II
		Targiniq ER	Oxycodone HCl and Naloxone	Schedule II

362. The RICO Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons, firms and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the RICO Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share and /or minimize the losses for the RICO Defendants.

363. The RICO Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

364. The RICO Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities the reality of the suspicious orders that the RICO Defendants were filling on a daily basis -- leading to the diversion of tens of millions of doses of prescription opioids into the illicit market.

365. The RICO Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

366. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

367. As described herein, the RICO Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenue from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims and methods of commission. The predicate acts were related and not isolated events.

368. The predicate acts all had the purpose of generating significant revenue and profits for the RICO Defendants, while Plaintiff was left with substantial injury to its business through the damage that the prescription opioid epidemic caused. The RICO Defendants committed or caused to be committed the predicate acts through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

369. The pattern of racketeering activity alleged herein, and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the enterprise.

370. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

371. RICO Defendants have hidden many of the precise dates of the criminal actions at issue here, and these cannot be alleged without access to Defendants' books and records. Indeed,

an essential part of the successful operation of the Opioids Addiction and Opioid Diversion Enterprise alleged herein depended upon secrecy.

372. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in this jurisdiction and the Plaintiff. Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on consumers in this jurisdiction, its citizens or the Plaintiff. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products. The Defendants were also aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

373. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

374. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiff by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

375. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

2. The RICO Defendants Manufactured, Sold and/or Dealt in Controlled Substances, and Their Crimes Are Punishable as Felonies

376. The RICO Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

377. The RICO Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 483(d)(1).

378. Each of the RICO Defendants qualifies as a registrant under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances, and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

379. The CSA and the Code of Federal Regulations required the RICO Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

380. The RICO Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders and/or omitted material information from reports, records and other documents they were required to file with the DEA, including the Manufacturer Defendants' applications for production quotas. Specifically, the

RICO Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

381. Federal authorities investigated McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form 8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay $150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.

382. The RICO Defendants engaged in a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74. The vast number of enforcement actions available in the public record against the Distributor Defendants supports this conclusion.

383. These actions against the Distributor Defendants confirm that the Distributor Defendants knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate, on information and belief, that the Manufacturer Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

384. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

385. Many of the precise dates of Defendants' criminal actions at issue herein were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential

part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

386. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in this jurisdiction and the Plaintiff. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens, or the Plaintiff. The Defendants were aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

387. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

388. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiff by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

389. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

D. DAMAGES

390. The RICO Defendants' violations of law and their pattern of racketeering activity

directly and proximately caused Plaintiff's injuries in its business and property because Plaintiff paid for costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference.

391. Defendants' racketeering activities proximately caused Plaintiff's injuries and those of its citizens. But for the RICO Defendants' conduct, Plaintiff would not have incurred the costs and expenditures required as a result of the plague of drug-addicted citizens.

392. The RICO Defendants' racketeering activities directly caused Plaintiff's injuries and those of its citizens.

393. Plaintiff was most directly harmed and there are no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

394. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorneys' fees and all costs and expenses of suit, and pre- and post-judgment interest.

COUNT V
RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ACT
18 U.S.C. 1962(d), *et seq.*
(Against All Defendants)

The Plaintiff incorporates Paragraphs 1 through 394 as if fully restated and set forth herein.

395. Plaintiff brings this claim on its own behalf against all RICO Defendants. At all relevant times, the RICO Defendants were associated with the Opioid Diversion Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d), it is unlawful for "any person to conspire to violate" Section 1962(d), among other provisions. 18 U.S.C. § 1962(d).

396. Defendants conspired to violate Section 1962(c), as alleged more fully above, by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity, as incorporated by reference below.

A. THE OPIOID DIVERSION ENTERPRISE

397. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set out above concerning the "Opioid Diversion Enterprise."

B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE

398. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set out above concerning the "Conduct of the Opioid Diversion Enterprise."

C. PATTERN OF RACKETEERING ACTIVITY

399. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set out above concerning the "Pattern of Racketeering Activity."

D. DAMAGES

400. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff's injuries in its business and property because Plaintiff paid for costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference.

401. Defendants' racketeering activities proximately caused Plaintiff's injuries and those of its citizens. But for the RICO Defendants' conduct, Plaintiff would not have incurred the costs and expenditures required as a result of the plague of drug-addicted patients and citizens.

402. The RICO Defendants' racketeering activities directly caused Plaintiff's injuries and those of its citizens.

403. Plaintiff was most directly harmed and there are no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

404. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia,* actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorneys' fees and all costs and expenses of suit, and pre- and post-judgment interest.

COUNT IX
RELIEF REQUESTED

Plaintiff incorporates Paragraphs 1 through 404 as if fully restated and set forth herein.

WHEREFORE, in consideration of the claims stated above, the Plaintiff in this case respectfully submits that upon a full hearing of the evidence that this Honorable Court, and the jury hearing this case, grant the following relief.

405. Judgment in favor of the Plaintiff against each Defendant separately and severally, based on joint and several liability, against each and every Defendant in this case;

406. An entry of equitable relief and Order of Abatement against the Defendants, jointly and severally, along with all those acting in concert with the Defendants including all agents, subsidiaries and all other persons acting in concert or participation with the Defendants from continuing the conduct made the subject of this Complaint.

407. An Order of Injunction against the Defendants on a permanent basis along with accompanying restitution.

408. An Order from this Court against the Defendants that they fully compensate Plaintiff for past and future expenses required to abate the nuisance caused by the opioid epidemic.

409. A judgement and award of compensatory damages, including without limitation, all damages previously outlined in this Complaint.

410. An award of pre-judgment and post-judgment interests.

411. In addition to the damages outlined herein, Plaintiff demands that Defendants pay court costs, including attorneys' fees, applicable interest and all other relief as allowed under Alabama law and as this Court deems appropriate and just.

412. Such other and further relief as the Court deems just and appropriate.

PLAINTIFF DEMANDS TRIAL STRUCK BY JURY

Respectfully submitted,

/s/ *Kimberly R. West*

Kimberly R. West (ASB -2419-E65K)
Roderick J. Evans (ASB-6391-E64E)
Wallace, Jordan, Ratliff & Brandt LLC
800 Shades Creek Parkway, Suite 400
Birmingham, AL 35244
kwest@wallacejordan.com
revans@wallacejordan.com

Attorneys for Plaintiff

CERTIFICATE OF SERVICE

Plaintiff requests the following be served by CERTIFIED MAIL by the Clerk of Court:

AMERISOURCEBERGEN DRUG CORPORATION
c/o CT Corporation System
2 North Jackson Street, Suite 605
Montgomery, AL 36104

CARDINAL HEALTH, INC.
c/o CT Corporation System
2 North Jackson Street, Suite 605
Montgomery, AL 36104

McKESSON CORPORATION
c/o Corporation Service Company
641 South Lawrence Street
Montgomery, AL 36104

TEVA PHARMACEUTICALS USA, INC.
TEVA PHARMACEUTICAL INDUSTRIES, LTD.
c/o Corporate Creations Network, Inc.
4000 Eagle Point Corporate Drive
Birmingham, AL 35242

CEPHALON, INC.
c/o Corporate Creations Network, Inc.
4000 Eagle Point Corporate Drive
Birmingham, AL 35242

JOHNSON & JOHNSON
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

JANSSEN PHARMACEUTICALS, INC.
c/o CT Corporation System
2 North Jackson Street, Suite 605
Montgomery, AL 36104

ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.
n/k/a JANSSEN PHARMACEUTICALS, INC.
c/o CT Corporation System
2 North Jackson Street, Suite 605
Montgomery, AL 36104

JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.
c/o CT Corporation System
2 North Jackson Street, Suite 605
Montgomery, AL 36104

ENDO HEALTH SOLUTIONS INC.
1400 ATWATER DRIVE
MALVERN PA 19355

ENDO PHARMACEUTICALS, INC.
c/o CT Corporation System
2 North Jackson Street, Suite 605
Montgomery, AL 36104

ALLERGAN PLC f/k/a ACTAVIS PLC/
ACTAVIS PHARMA, INC., ACTAVIS LLC
n/k/a Allergan USA, Inc.
c/o Corporate Creations Network, Inc.
4000 EAGLE POINT CORPORATE DRIVE
BIRMINGHAM, AL 35242

WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.
c/o Corporate Creations Network, Inc.
4000 EAGLE POINT CORPORATE DRIVE
BIRMINGHAM, AL 35242

NORAMCO, INC.
c/o CT Corporation System
2 North Jackson Street, Suite 605
Montgomery, AL 36104

WATSON LABORATORIES, INC., subsidiary of TEVA
c/o Corporate Creations Network, Inc.
4000 Eagle Point Corporate Drive
Birmingham, AL 35242

ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.
c/o Corporate Creations Network, Inc.
4000 Eagle Point Corporate Drive
Birmingham, AL 35242

PAR PHARMACEUTICAL, INC.
c/o CT Corporation System
2 North Jackson Street, Suite 605
Montgomery, AL 36104

PAR PHARMACEUTICAL COMPANIES, INC. f/k/a PAR PHARMACEUTICAL HOLDINGS, INC., owned by Endo
c/o CT Corporation System
2 North Jackson Street, Suite 605
Montgomery, AL 36104

WEST-WARD PHARMACEUTICALS CORP.
WEST-WARD PHARMACEUTICAL CORP.
n/k/a HIKMA Pharmaceuticals USA Inc.
c/o CT Corporation System
2 North Jackson Street, Suite 605
Montgomery, AL 36104

MYLAN PHARMACEUTICALS, INC.
c/o CT Corporation System
2 North Jackson Street, Suite 605
Montgomery, AL 36104

MYLAN BERTEK PHARMACEUTICALS INC.
c/o CSC- Lawyers Incorporating Service, Inc.
150 South Perry Street
Montgomery, AL 36104

INDIVIOR INC.
641 South Lawrence Street
Montgomery, AL 36104

WALGREENS BOOTS ALLIANCE, INC. a/k/a WALGREEN CO.
108 Wilmot Road
Deerfield, IL 60015

WALMART INC f/k/a WAL-MART STORES, INC.
c/o CT Corporation System
2 North Jackson Street, Suite 605
Montgomery, AL 36104

CVS HEALTH CORPORATION
c/o CT Corporation System
2 North Jackson Street, Suite 605
Montgomery, AL 36104

s/ Kimberly R. West
Of Counsel